REMARKS

Please amend claim 1 as indicated in the listing of claims. The amendments and additions add no new matter as the claim language is fully supported by the specification and original claims.

Applicant submits that pending claims 1 and 5-15 are in condition for allowance, and respectfully requests that the claims as amended be entered.

Rejections under 35 U.S.C. §112, First Paragraph

Claims 1 and 5-15 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse the rejection as it applies to the amended claims.

The Office Action alleges that the claims "read on using any BMP-1 having any structural feature and any myostatin having no structural feature used in the claimed method." (Office Action, page 4.) Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 1 to limit the metalloprotease to mammalian bone morphogenic protein-1 (BMP-1). Applicants have also amended claim 1 to recite that the myostatin complex comprises SEQ ID NO: 2, SEQ ID NO:4, SEQ ID NO: 6 or SEQ ID NO: 8. Support for the amended claim language may be found at, among others, paragraph [0036] and Example 4 of the specification as filed.

Applicants submit that the amended claim complies with the written description requirement, and as such, withdrawal of the rejection is respectfully requested.

Claims 1 and 5-15 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully traverse the rejection as it applies to the amended claims.

Specifically, the Office Action alleges that the specification is not enabling for a method of "modulating any myostatin activation, comprising contacting any latent myostatin complex

comprising any myostatin pro-peptide and any myostatin C-terminal fragment, by using any BMP-1 metalloprotease that can cleave the myostatin pro-peptide, with any agent that increases or decreases proteolytic cleavage of the pro-peptide by the metalloprotease, thereby modulating myostatin activation." (Office Action, page 6.) Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 1 to limit the metalloprotease to mammalian bone morphogenic protein-1 (BMP-1). Applicants have also amended claim 1 to recite that the myostatin complex comprises SEQ ID NO: 2, SEQ ID NO:4, SEQ ID NO: 6 or SEQ ID NO: 8. Support for the amended claim language may be found at, among others, paragraph [0036] and Example 4 of the specification as filed. Accordingly, Applicants respectfully submit that the specification satisfies the enablement requirement with regard to the amended claims. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §102

Claims 1 and 5-15 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Lee et al. (U.S. PGPUB 2002/0157126A1; hereinafter, "Lee"). Applicants respectfully traverse the rejection as it applies to the amended claims.

To anticipate, a single reference must expressly teach each and every element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131. Furthermore, the reference must be enabling (*see e.g., Chester v. Miller*, 15 U.S.P.Q.2d 1333 (Fed. Cir. 1990)).

The Office Action alleges that Lee discloses a "method of modulating a [Sic] myostatin activation, comprising contacting a latent myostatin complex comprising a myostatin pro-peptide and a myostatin C-terminal fragment and BMP-1 that can cleave the myostatin pro-peptide into prodomain … with an agent that decreases proteolytic cleavage of the pro-peptide by the BMP-1, thereby modulating myostatin activation." (Office Action, page 10.)

Amended claim 1 recites a method of modulating myostatin activation, comprising contacting a latent myostatin complex comprising a myostatin pro-peptide and a myostatin

C-terminal fragment, and a metalloprotease that can cleave the myostatin pro-peptide, wherein the metalloprotease is mammalian bone morphogenic protein-1 (BMP-1), with an agent that increases or decreases proteolytic cleavage of the pro-peptide by the metalloprotease, wherein the myostatin complex comprises SEQ ID NO: 2, SEQ ID NO:4, SEQ ID NO: 6 or SEQ ID NO: 8, and wherein the agent is a peptide consisting of SEQ ID NO: 9.

A review of the cited reference indicates that nothing in the reference teaches or suggests a method of modulating myostatin activation. The data presented in Lee demonstrates that myostatin is negatively regulated by follistatin, which binds the C-terminal dimmer and inhibits its ability to bind to receptors. The reference indicates that, "[r]elease of the C-terminal dimmer from these inhibitory proteins by unknown mechanisms allows myostatin to signal through activin type II receptors." (Lee, paragraph [0364]). Applicants respectfully submit that Lee is absolutely silent with regard to the identification of a metalloprotease that can cleave the myostatin pro-peptide, and is further silent with regard to any agents that increase proteolytic cleavage of the pro-peptide by the metalloprotease. Finally, Lee is absolutely silent with regard to the identification of SEQ ID NO: 9 for use as the agent that increases or decreases proteolytic cleavage of the pro-peptide by the metalloprotease, as required by the amended claims.

Accordingly, Applicants respectfully submit that Lee fails to teach each and every element of the claimed invention, and request withdrawal of the rejection.

CONCLUSION

In summary, for the reasons set forth herein, Applicants submit that the pending claims clearly and patentably define the invention and respectfully request that the Examiner withdraw all rejections and pass the application to allowance. If the Examiner would like to discuss any of the issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

The Commissioner is hereby authorized to charge the total amount of $490.00 as payment for the Two-Month Extension of Time fee, large entity, to Deposit Account No. 07-1896. No other fee is deemed necessary with the filing of this paper. However, the Commissioner is further authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-referenced Attorney docket number.

Respectfully submitted,

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